K121948

JUL 20 2012

510(K) SUMMARY
Agfa Computed Radiography (CR) Systems with CR 10-X Digitizer

Common Name: Computed Radiography System
Classification Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Classification: 21 CFR 892.1650
Product Code: MQB
Proprietary Name: Computed Radiography (CR) Systems with CR 10-X Digitizer
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Phil Cuscuna, Prepared: April 10, 2012
Telephone: (416) 240-7317
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A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's Computed Radiography (CR) System with CR 10-X Digitizer, a solid state x-ray imaging device. It is substantially equivalent to systems with Agfa's CR 30-X digitizer (K062223).

B. DEVICE DESCRIPTION

Agfa's Computed Radiography (CR) Systems with CR 10-X Digitizer is a solid state x-ray imaging device. Principles of operation and technological characteristics of the new and predicate devices are largely the same as other computed radiography systems:

- Phosphor coated imaging plates and cassettes for image capture.
- Laser digitizer for generating the electronic image.
- NX workstation for image previewing, processing and routing

C. INTENDED USE

Agfa's Computed Radiography (CR) System with CR 10-X Digitizer is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The system may be used wherever conventional screen-film systems are used.

Agfa's Computed Radiography (CR) System With CR 10-X Digitizer is not indicated for use in mammography.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's Computed Radiography (CR) System with CR 10-X Digitizer has an Indications For Use statement similar to the statement for the predicate device, K062223. Intended uses are the same. The devices have the same technological characteristics. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

PRODUCT COMPARISON TABLE		
	Systems with CR 10-X Digitizer (New Device)	**Systems with CR 30-X Digitizer (PREDICATE-K062223)**
Communications	Same as predicate	DICOM
Cassette and Image Plates		
Cassettes and Image Plate Sizes	35x43 cm	15x30 cm 18x24 cm 24x30 cm 35x35 cm 35x43 cm
Image Plate Phosphors	Same as predicate	BaSrFBrI:Eu
Digitizer		
Scanning technology	Same as predicate	Point at-a-time
Light collection	Same as predicate	Solid, high efficiency
Scanning resolution	Same as predicate	100µ
Active matrix	3420 x 4218	3480 x 4248
Dynamic range (acquisition)	Same as predicate	16 bit, sq. root compressed
Throughput (35x43 cm plates/hr.)	34	60
Power Supply	Same as predicate	100 – 240V 50/60 Hz
Mobile installations	Same as predicate	Mobile mounting option
Image stitching	Same as predicate	Full Leg Full Spine
Workstation		
Image processing	Same as predicate	MUSICA, MUSICA^2
Dynamic range (display)	Same as predicate	12 bit
Operating system	Windows 7	Windows XP Pro
Power Supply	Same as predicate	100 – 240V 50/60 Hz
Display System	Same as predicate	Standard PC display or separately cleared medical display

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's Computed Radiography (CR) Systems with CR 10-X Digitizer is a solid state x-ray imaging device. It uses phosphor coated imaging plates to capture an x-ray exposure. Upon scanning of the image plates by the CR-10-X digitizer, the x-ray image is read and transmitted to the NX workstation where the image can be previewed, processed and transmitted to other devices for viewing, printing or storage.

F. TESTING

The device has completed verification and validation testing to confirm it meets specifications and operates as planned. Tests included image quality tests with internal and external experts comparing the device to its predicate.

The product, manufacturing and development processes have been shown to conform to product safety, radiology, and imaging standards including:

PRODUCT STANDARDS

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, plus collateral standard: Electromagnetic compatibility - requirements and tests.
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- ACR/NEMA PS3.1-3.18: Digital Imaging and Communications in Medicine (DICOM)

MANAGEMENT STANDARDS

- ISO 14971 Application of Risk Management to Medical Devices
- ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Agfa Healthcare N.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUL 20 2012

Re: K121948
Trade/Device Name: CR 10-X Digitizer
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 2, 2012
Received: July 3, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121948

Device Name: CR 10-X Digitizer

Indications for Use:

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Prescription Use ___X___		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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